



**California State Board of Pharmacy**

400 R Street, Suite 4070, Sacramento, CA 95814-6237

Phone (916) 445-5014

Fax (916) 327-6308

Website - [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

## **REQUIREMENTS FOR FILING AN APPLICATION FOR NONRESIDENT PHARMACY STERILE COMPOUNDING LICENSE**

(Business & Professions Code §4127 et. seq.)

Effective July 1, 2003, a nonresident pharmacy may not compound injectable sterile drug products for shipment into California unless:

1. The nonresident pharmacy is licensed with the board as an injectable sterile drug compounding nonresident pharmacy, OR:
2. The nonresident pharmacy is operated by an entity that is licensed as a hospital, have health agency, or a skilled nursing facility, and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or another accreditation agency approved by the board (at the current time there is no other agency).

Nevertheless all nonresident pharmacies that compound injectable sterile drug products and ship these products into California must follow board regulations for injectable sterile drug compounding. These regulations are found in Title 16 California Code of Regulations as Article 8, beginning with section 1751.

A license for a nonresident pharmacy to compound injectable sterile drug products may only be issued for a location that is separately licensed as a nonresident pharmacy, and may only be issued to the owner of the nonresident pharmacy licensed at that location.

### **For a complete application, the following items must be submitted:**

1. A completed and signed Application for Nonresident Sterile Compounding Pharmacy License (Form 17A-50).
2. Fee of \$500, made payable to "CA Board of Pharmacy."
3. A copy of an inspection report issued by the pharmacy's licensing agency within the prior 12 months, documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.
4. A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding on disk, CD, or via email. If emailing the policies and procedures, please send to [CompoundingPharmacy@dca.ca.gov](mailto:CompoundingPharmacy@dca.ca.gov).
5. Corporate officer, owner, or partner who signed the application will need to complete the enclosed fingerprint cards.

**\*\* Effective January 1, 2001, the Board of Pharmacy requires all applicants for a new license to have not only a California Department of Justice (DOJ) criminal record check but also a federal background check. No license will be issued without background clearances from both agencies.**

## **Fingerprint Requirements**

### **California Residents**

The board will only accept Live Scan Service Forms from California residents.

***Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning.*** Please refer to the Instructions for completing a "Request for Live Scan Service" form. Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice website at <http://caag.state.ca.us/app/contact.pdf> or the sources listed on the bottom of the instructions for completing a "Request for Live Scan Service" form.

The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach the second copy of the form to your application and submit to the board.

### **Non California Residents**

If an owner, partner, corporate officer, major shareholder or director reside out of state they must submit rolled fingerprints on cards provided by the board and include a separate fee of \$66 (\$32 California Department of Justice (DOJ) fee, \$10 DOJ expedite fee and \$24 FBI fingerprint processing fee). (Live Scan processing fees are paid directly at the Live Scan site.) You may contact the board to request fingerprint cards at (916) 445-5014. You may also request cards on our website at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

Fingerprints submitted on cards should be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take approximately six weeks (live scan is faster). Poor quality prints may result in rejection and will substantially delay licensing as additional fingerprint cards will be required from you for processing.

The board will only accept fingerprint cards from residents outside of California.



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## APPLICATION FOR NONRESIDENT PHARMACY STERILE COMPOUNDING LICENSE

*Please print or type*

**ALL BLANKS MUST BE COMPLETED; IF NOT APPLICABLE, ENTER N/A**

Name of Pharmacy:			Pharmacy License Number	
Pharmacy Telephone Number:		Sterile Compounding Telephone Number: (if different)		
Address of Pharmacy:	Street and Number	City	State	Zip Code

Name of pharmacist-in-charge of licensed pharmacy:			Pharmacist license number	
Residence address:	Street and Number	City	State	Zip Code

Indicate whether this application is for:				
<input type="checkbox"/> New Licensed Sterile Compounding License	<input type="checkbox"/> Change of Location of Licensed Sterile Compounding pharmacy	<input type="checkbox"/> Change of Ownership of Licensed Sterile Compounding pharmacy		
If this is a <b>change of ownership</b> or <b>change of location</b> , indicate previous name, address and license number of compounding pharmacy.				
Name:		Address:		License Number:
Please indicate type of ownership:				
<input type="checkbox"/> Individual	<input type="checkbox"/> Partnership	<input type="checkbox"/> Corporation	<input type="checkbox"/> Not-for-profit corporation	<input type="checkbox"/> Limited Liability

I certify that the policies and procedures of the sterile compounding are consistent with California Code of Regulations Title 16, section 1751 et seq.

\_\_\_\_\_  
Signature of Pharmacist-in-Charge

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Date

CONTINUE ON REVERSE		
FOR OFFICE USE ONLY		
STAFF REVIEW	CASHIER LOG	
<input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ Referred for inspection: _____ Inspection Completed: _____	Approved _____ Denied _____ Date _____	Cashier # _____ Date _____ Amount of fee _____

## Ownership Information

<b>If a Sole Ownership:</b>				
Name of Sole Owner		*Social Security Number		Telephone Number
Address      number and street		City	State	Zip Code
<b>If a Partnership: (attach additional sheet if needed)</b>				
Name of Partner		*FEIN Number		Telephone Number
Address      number and street		City	State	Zip Code
Name of Partner		*FEIN Number		Telephone Number
Address      number and street		City	State	Zip Code
<b>If a Corporation: (attach additional sheet if needed)</b>				
Name of Corporation (If applicable)				Telephone Number
Address      number and street		City	State	Zip Code
<p>Print below the name, title, address and license number of all the pharmacy owners. This includes the individual owner, all partners, corporate officers. Under the heading "Licensed as" list any state professional or vocational licenses held; e.g., pharmacist, physician, podiatrist, dentist or veterinarian etc., and license number. Non-profit organizations must list the names and titles of persons holding corporate positions. Attach additional sheets if necessary.</p>				
Title	Name	Residence Address	Social Security Number	Licensed as and license number

\*Disclosure of your social security number (or federal employer identification number ("FEIN"), if you are a partnership) is mandatory. Section 30 of the Business and Professions Code and Public Law 94-455 (42 USCA 405(c)(2)(C) authorize collection of your social security number. Your social security number or FEIN will be used exclusively for tax enforcement purposes or compliance with any judgment or order for family support in accordance with section 17520 of the Family Code. If you fail to disclose your social security number or your FEIN, your application for initial or renewal license will not be processed AND you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

Federal Employer Identification Number\*

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## PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a Nonresident Pharmacy Sterile Compounding License will be issued.

If changes are made during the application process, you may need to submit a new application with the appropriate fees. **Any application not completed within 60 days after you have been notified by the board of deficiencies in your file, may be deemed to have been abandoned, and you may be required to file a new application and meet all the requirements which are in effect at the time of application. Fees applied to this application are not transferable and are non refundable.**

Any material misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of a license, and is a violation of the Penal Code of California. All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete.

The information will be used to determine qualifications for licensure under California Pharmacy Law. The officer responsible for information maintenance is the Executive Officer, (916) 445-5014, 400 R Street, Suite 4070, Sacramento, California 95814. The information may be transferred to another governmental agency (such as a law enforcement agency) if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted from disclosure by the California Information Practices Act. (Civil Code §1798, et seq.)

Under penalty of perjury, under the laws of the State of California, the person whose signature appears below, certifies and says that: (1) he/she is the owner or an officer of the applicant corporation named in the foregoing application, duly authorized to make this application on its behalf and is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) no person other than the applicant has any direct or indirect interest in the applicant's business to be conducted under the license(s) for which this application is made; (4) all supplemental statements are true and accurate. I am also aware that I am bound by the applicable Federal and State laws and regulations pertaining to the practice of pharmacy.

Signature of Corporate officer, owner, or partner

Name (please print)

Title

Date

Mail all correspondence to the following address below. If correspondence should be mailed to the pharmacy please insert "Same as Pharmacy."

Name and telephone number of contact person to clarify information provided on this application.

e-mail address

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